



PATENT  
Docket No.: 1662/492021

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Reissue of U.S. 6,365,574 B2

In Re Reissue Application of:

Applicant: Claude SINGER et al.

Serial No. 10/816,376

Filed: April 2, 2004

Group Art Unit: 1623

Examiner: E. Peselev

For: ETHANOLATE OF AZITHROMYCIN, PROCESS FOR  
MANUFACTURE, AND PHARMACEUTICAL COMPOSITIONS  
THEREOF

Assistant Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**DECLARATION OF JUDITH ARONHIME PURSUANT TO 37 C.F.R. §1.132**

I, JUDITH ARONHIME, Ph.D., of Harav Maor Yosef str. 5a, Rehovot 76217, Israel,  
declare as follows:

1. I am a named inventor of the above-identified reissue application ("the '376 reissue application"). The '376 reissue application seeks reissue of U.S. Patent No. 6,365,574 ("the '574 patent"), for which I am also a named inventor.
2. I received my Ph.D. and M.Sc. degrees in 1989 and 1983, respectively, from The Hebrew University of Jerusalem, Casali Inst. of Applied Chemistry. Since 1991, I have worked for Teva Pharmaceutical Industries, Ltd. ("Teva"). I am currently Teva's Global Solid State Characterization Manager. In that position, I am responsible for the physical analysis and characterization of drugs developed by

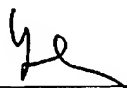
Teva API ("Active Pharmaceutical Ingredients"). I am responsible for over 25 analysts in the group.

3. I have review the Office Action dated August 12, 2007, the cited Chinese Patent (CN 1161971), the application and the pending claims.
4. Crystallization solvent molecules may or may not become incorporated into the unit cell of a crystallized compound. It is highly dependent on the nature of the compound and the crystallization conditions.
5. Example 1 of the Chinese patent discloses a crystallization of azithromycin from acetone only. The product of this crystallization therefore cannot be an ethanolate of azithromycin because no ethanol is present in the reaction mixture.
6. The Chinese patent states that it obtained a single form of azithromycin using various organic solvents. Therefore, since the crystallized azithromycin in Example 1 cannot be an ethanolate of azithromycin, the crystallized azithromycin in Example 2 cannot be an ethanolate of azithromycin.
7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and believe are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated:

27.1.08


Signed:

  
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Judith Aronhime, Ph.D.

Applicants submit that the pending claims are in condition for allowance. The Examiner is invited to contact the undersigned at 202-220-4200 to discuss any matter regarding this application.

Respectfully submitted,

Date: February 4, 2008

By:   
W. David Wallace  
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